



**New Jersey Department of Health and Senior Services  
Governor's Council for Medical Research and Treatment of Autism  
Meeting Minutes – May 21, 2012, 6pm – 9pm (ratified)**

**Council Members Present**

Elizabeth K. Bell, BS, volunteer and independent contractor with Autism Speaks,  
Autism Organization Representative

Caroline Eggerding, M.D., Healthcare Organization Representative and Chairperson of the  
Governor's Council for Medical Research and Treatment of Autism

Susan P. Evans, Ed.D., Education Program Specialist for Early Intervention Program,  
Commissioner of Health and Senior Services Appointee

B. Madeleine Goldfarb, MA, Founder/Director of the Noah's Ark Children's Association,  
Autism Organization Representative

Ketan Kansagra, M.D., FAAP, Children's Hospital of New Jersey at Newark Beth Israel Medical  
Center, Academic Institution Representative

Linda S. Meyer, Ed.D., MPA, BCBA-D Executive Director of Autism New Jersey, Autism  
Organization Representative

Gary Weitzen, BA, Executive Director, Parents of Autistic Children (POAC) Autism Services,  
Organization Representative

**Absent**

Matthew Cortland, BA, Instructor, Teach for America, Public Member

Grace M. Reilly, RN, MSN, APN-C, Adult Nurse Practitioner for Riverview Medical Center,  
Individual with Autism or Family Member Representative

Judah Zeigler, Senate President Appointee

## **NJ Department of Health and Senior Services (DHSS) Attendees**

Martin T. Zanna M.D., MPH  
Acting Executive Director  
Governor's Council for Medical Research and Treatment of Autism

Cynthia Kirchner, MPH  
Director, Quality Improvement  
Ethics Liaison for the DHSS

Linda N. Bocclair, M.Ed., MBA  
Executive Assistant  
Governor's Council for Medical Research and Treatment of Autism

Mary Ray, Contract Administrator 2  
Governor's Council for Medical Research and Treatment of Autism  
Commission on Brain Injury Research  
Commission on Spinal Cord Research

Daphne Robinson, Ph.D., Consultant  
Scientific Planning Consulting

## **General Public Attendees**

Jonathan Sabin  
Josephine Shenouder  
Pnina Mintz, Ph.D.  
Audrey Mars, M.D.

**I. Welcome** - Council Chairperson, Dr. Caroline Eggerding called the meeting to order at 6:10 PM and welcomed everyone.

**II. Public Meetings Act Announcement**- Dr. Eggerding read the Public Meetings Act, followed by roll call.

## **III. Approval of the March 5, 2012 Council Meeting Minutes**

Dr. Eggerding called for a motion to approve the minutes. MOTION by Ms. Goldfarb to approve the minutes was seconded by Mr. Weitzen.

MOTION to approve the minutes was passed with all in favor.

#### **IV. New Jersey Autism Center of Excellence (NJ ACE) Grant Applications– Discussion and Voting**

Dr. Eggerding began the discussion with the following points for the Council to consider as they discuss and vote on the grant applications: 1) the Council's meeting agenda does not include an item for public comments; this is a working meeting, not a typical Council meeting; 2) while it may be difficult, given that grant applicants may be present in the audience, the Council is encouraged to refrain from addressing questions to the audience; 3) grant applications will be identified by grant number and then, if additional information is needed, the title of the grant application will be referenced but not the name of the Principal Investigator; 4) members should keep in mind the effort that has gone into developing the Request for Applications (RFA) relating back to Council's retreat in 2009 with discussions about the Clinical Enhancement Centers and a New Jersey Autism Center of Excellence (NJ ACE). The RFA process has been lengthy and detailed as it evolved to where it is today. Applications for the NJ ACE Coordinating Center and Program Sites have gone through a thoughtful assessment and analysis by a fifteen (15) member Scientific Merit Review Panel consisting of national experts in autism clinical research and treatment. The Panel recommended funding only those applications that scored equal to or less than 3.0 with 1.0 being the highest possible score on the National Institutes of Health (NIH) scale of 1 to 9.

#### **V. Comments by Ms. Cynthia Kirchner, Director of Quality Improvement and Ethics Liaison.**

Ms. Kirchner reviewed the rigorous process leading up to this evening when Council votes to approve grant applications for funding. Dr. Daphne Robinson provided consultation to the Council's staff throughout the development of the RFAs, the selection of the Scientific Merit Review Panel and responses to questions from applicants. The review process included the in-house administrative review to ensure completeness and accuracy and compliance with New Jersey regulations followed by the relevance review as defined in the Grant Guidelines.

Drs. Robinson and Zanna worked to pair each application with three reviewers who were highly qualified based on their areas of expertise. The reviewers submitted their critiques through the NJ State System for Administering Grants Electronically (SAGE) and met on April 30, 2012 to present their critiques to the group. Applications were either triaged or scored following the NIH grant review process. Drs. Zanna and Robinson, Ms. Ray and Ms. Bocclair attended the meeting and assisted, as appropriate. One of the Panel members chaired the meeting. The results of the scoring are listed on the leaderboards in the Council's meeting packets; one for the program site applications and one for the coordinating center applications. Drs. Zanna and Robinson discussed the results with the Scientific Advisory Committee (SAC) and will discuss their recommendations with the Council. Ms. Kirchner reminded Council of the importance of funding only the best applications. The reviewers felt strongly that only those applications scoring 3 or lower (1-9 NIH scoring with 1 being the highest score) should be funded to ensure that the best research is funded. Ms. Kirchner proposed that although \$8M is available for funding, that not all funding need be determined at the meeting and that a revised RFA can be reissued for the remainder of the funding. If the RFA were to be reissued in early July with three months for applicants to respond grants could be awarded by the end of 2012. This would enable

the applicants who were not funded to revise their applications based on the critiques by the reviewers and reapply. We anticipate that new applicants will also apply.

After a brief discussion it was agreed to reissue a revised RFA if Council did not award \$8M in funding during the meeting. The core of the original RFA would not change, only the language of the IACC objectives to reflect Council's interest in funding clinical research with the potential for more direct clinical impact to help individuals with ASD.

## **VI. NJ ACE Grant Applications – discussion and voting**

Ms. Ray described the process for discussion and voting on the grant applications. For each application Council members make a motion to accept the recommendation of the Scientific Merit Review Panel and then discuss the application. The motion can be modified, accepted or rejected.

Ms. Ray distributed the Conflict of Interest form to Council with a request to complete the form if any member had a conflict of interest with any of the applications. If there is a conflict the member must leave the room during the discussion of the application. There were no conflicts of interest reported by the Council members.

### **CAUT12ACC012-Coordinating Center**

This is the one application for the NJ ACE Coordinating Center recommended for funding by the Scientific Merit Review Panel. There was a general consensus among the Council that this was a strong application. The score by the Scientific Merit Review Panel reflected their enthusiasm for the expertise of the investigators and staff, the environment and the overall presentation. The applicant has an excellent program evaluation plan and a highly regarded evaluator.

In response to the concerns expressed, relative to the applicant's experience in having conducted evidenced-based clinical programs, the role of the Coordinating Center was clarified. The coordinating center grantee is primarily responsible for management functions with demonstrated experience and success with startups. Montclair State University received the top score by the Scientific Merit Review Panel, fulfilling all of the criteria for a top rated Coordinating Center as defined by the RFA. They will bring researchers together to build a community of autism researchers with a forum for discussing best practices in clinical research and other issues as identified by the Program Sites. The Program Sites are recognized as the experts in clinical research in autism.

This clarification mitigated concerns raised by members relative to Montclair's becoming operational and their being an insufficient time commitment of medical expertise to support the project, despite the recognized excellence of staff available to this relatively new program. One member commented that she was pleased to see that an organization that Council had not worked with previously had applied and she was looking forward to new perspectives and ideas.

It was noted that the Scientific Merit Review Panel members who critiqued the Coordinating Center applications have extensive experience with the operation and evaluation of Coordinating

Centers or similar entities. They were selected differently from those who critiqued the Program Site applications.

While funding is awarded for five years, grantees will present progress reports on an annual basis to qualify for continuation funding. At the end of five years Council can decide to refund the Coordinating Center or issue a new RFA depending on Council's plan for funding. Another possibility is that the Coordinating Center will build a name for itself and secure federal funding. It is important to note that there will be ongoing evaluation of the grantees and feedback from the Council to the grantees.

Council proceeded to vote on all applications that were scored keeping in mind the recommendation to approve only those applications scoring between 1 and 3. While Council can vote to approve applications scored above 3 (4 to 9) the process will change. A motion to accept the recommendation of the Scientific Merit Review Panel can be modified, accepted or rejected. A motion can also be tabled if several applications score high (1 to 3) and reevaluated after all applications are discussed.

Dr. Eggerding called for a motion. MOTION by Mr. Weitzen to accept the recommendation of the Scientific Merit Review Panel to fund CAUT12ACC012 was seconded by Ms. Goldfarb.

MOTION to accept the recommendation of the Scientific Merit Review Panel to fund CAUT12ACC012 was passed with six in favor and one no vote.

#### **CAUT12ACC007- Coordinating Center**

Dr. Eggerding called for a motion. MOTION by Dr. Evans to accept the recommendation of the Scientific Merit Review Panel not to fund CAUT12ACC007 was seconded by Ms. Goldfarb.

Discussion: Considering the overall strength of the application, members commented on the possibility of the applicant reapplying as a program site applicant when the revised RFA is reissued.

MOTION to approve the recommendation of the Scientific Merit Review Panel not to fund CAUT12ACC007 was passed with all in favor.

#### **CAUT12ACC009- Coordinating Center**

Dr. Eggerding called for a motion. MOTION by Ms. Goldfarb to approve the recommendation of the Scientific Merit Review Panel not to fund CAUT12ACC009 was seconded by Dr. Evans. No discussion.

MOTION to approve the recommendation of the Scientific Merit Review Panel not to fund CAUT12ACC009 was passed with all in favor.

#### **CAUT12APS006-Program Site**

Dr. Eggerding called for a motion. MOTION by Ms. Goldfarb to approve the recommendation of the Scientific Merit Review Panel to fund CAUT12ACC006 was seconded by Dr. Evans.

Discussion: This was the only program site that scored within the 1-3 range and recommended for funding by the Scientific Merit Review Panel. The strengths of the application include their experienced team, a great environment and good follow up on a linkage study. The focus on SLI is innovative. Concerns expressed were that this applicant already has federal funding and the Council's intent is to support researchers who are not federally funded and prepare them to compete for federal funding. On the other hand, this applicant could move others along. Additional concerns were that the size of the cohort was small compared to the level of funding, and the impact on patients and on the future is unclear. Council had the option of recommending full funding, full funding with conditions, partial funding or no funding. Given that the application had gone through a rigorous evaluation process based on the requirements of the RFA and was recommended for funding, Council agreed to full funding without conditions. The Council did request that the applicant respond to the comments by the reviewers.

MOTION to approve the recommendation of the Scientific Merit Review Panel to fund CAUT12ACC006 was passed with all in favor.

#### **CAUT12APS015- Program Site**

Dr. Eggerding called for a motion. MOTION by Ms. Bell to approve the recommendation of the Scientific Merit Review Panel not to fund CAUT12APS015 was seconded by Ms. Goldfarb.

Discussion- Concerns expressed included the subcontract with an out of state research university, questionable importance of the topic for research and the lack of preliminary data for a major research project (more suited to a pilot project).

MOTION to approve the recommendation of the Scientific Merit Review Panel not to fund CAUT12APS015 was passed with all in favor.

#### **CAUT12APS019 - Program Site**

Dr. Eggerding called for a motion. MOTION by Ms. Bell to approve the recommendation of the Scientific Merit Review Panel not to fund CAUT12APS019 was seconded by Ms. Goldfarb.

Discussion-Members commented on the critiques by the reviewers with one reviewer praising the application and the second reviewer and the reader citing perceived major flaws. The applicant is strongly encouraged to address the critiques and reapply when the RFA is reissued. While the proposed research is extremely important and exciting and can result in outcomes applicable to clinical practice, the application was felt not to be well written. This could be a highly competitive application if all comments by the reviewers are addressed and the application is well written, perhaps by one person.

MOTION to approve the recommendation of the Scientific Merit Review Panel not to fund CAUT12APS019 was passed with all in favor.

#### **CAUT12AP024- Program Site**

Dr. Eggerding called for a motion. MOTION by Ms. Bell to approve the recommendation of the Scientific Merit Review Panel not to fund CAUT12APS024 was seconded by Ms. Goldfarb.

Discussion: Comments were made that the Council does not want to see more epidemiological studies where prevalence is not linked to etiology or treatment. Such surveillance studies have been funded by the Council.

MOTION to approve the recommendation of the Scientific Merit Review Panel not to fund CAUT12APS024 was passed with all in favor.

The remaining Program Site applications were triaged and, as such, were not discussed by Council.

### **Next steps**

The applications approved by Council for funding will be processed and the applicants will receive notification on June 1, 2012. A press release will be issued and staff will work with Council on an event to announce the grant awards. First Lady Mary Pat Christie will be invited to the event.

A revised RFA will be issued in July to fund up to two additional program sites by the end of 2012. Once the RFA is issued the ad hoc committee charged with recommending additional categories for funding can resume its work and recommend funding categories such as fellowships and pilot studies. Both the Scientific Advisory Committee (SAC) and the Scientific Merit Review Panel recommended these categories if the Council were to use such an approach as a strategy to nurture researchers. Dr. Kansagra, Chairperson for the ad hoc committee, can consult with Dr. Robinson to facilitate discussions with the committee. The committee will report to Council at the September 10, 2012 meeting.

## **VII. Report of the Acting Executive Director, Martin T. Zanna, M.D.,MPH**

### **Administrative Issues**

Four Council members have not updated their ethics training. Ms. Bocclair will send reminders next week. The Ethics Commission requests that all Special State Officers and State employees update their training on an annual basis.

Regarding the State Policy Prohibiting Discrimination in the Workplace, two members have not submitted the Acknowledgment of Receipt Forms. Members of Boards, Councils and Commissions that operate within the Department of Health and Senior Services are expected to adhere to the State Policy. Ms. Bocclair has the forms and requests that you sign and submit them to her at this meeting.

Ms. Barbara Morvay resigned from Council on May 3, 2012. She has retired and is spending time out of state and is unable to attend the meetings. She had hoped to be able to devote the necessary time and commitment but finds that it is not possible. She wishes the best for Council.

There are currently four open seats on the Council; three for academic institution representatives and one for Assembly Speaker Appointee. Council is encouraged to send

recommendations for membership to Ms. Bocclair.

### Scientific Advisory Committee (SAC)

The SAC met via conference call on May 2, 2012 to discuss the NJ ACE reviewers' critiques and provide input for Council's consideration. Four of the five members participated. Dr. Buxbaum was unable to participate. Having been provided copies of each proposal's abstracts and the critiques prepared by the Scientific Merit Review Panel, the SAC members were well positioned to comment. The SAC was in agreement with the review panel on those proposals recommended for triage. They also were in agreement with the Scientific Merit Review Panel's recommendation that only proposals that scored 3 or less (1 being the highest possible score) should be considered for funding.

### March 23, 2012 Scientific Meeting of the Council funded Research Grantees

The scientific meeting of the basic and clinical science researchers funded by the Council was held on Friday March 23, 2012 at the Holiday Inn in East Windsor. Council members in attendance included Madeleine Goldfarb, Liz Bell, Linda Meyer and Susan Evans. Dr. Zanna presented opening comments and then introduced Ms. Goldfarb who welcomed the attendees and provided a dynamic and inspiring overview with respect to plans for the day. The morning session included a presentation on "Autism Research: Strengths and Needs in New Jersey" by Dr. Dorothy Gaboda, Rutgers Center for State Health Policy

Following Dr. Gaboda's presentation, Dr. Zanna provided an update on Council activities followed by the interdisciplinary discussion groups. After lunch, the groups presented their findings in a general plenary session. A preliminary report was provided to the ad hoc committee that was charged with recommending categories for \$2M in funding for FY13. The preliminary report and comments from attendees is included in your folder. Ms. Bocclair and Ms. Goldfarb are compiling the proceedings from the meeting.

### **VIII. 2013 Meeting calendar**

Council discussed the best time(s) of the day to schedule meetings and questioned if afternoon meetings would enable members to attend on a regular basis. After a brief discussion it was decided that the selection of evening meetings, although not ideal for all members, is the best compromise. Members who are absent will be polled to ask if the time is the reason they cannot attend the meetings. Council would not want to change the time if it meant that one or more members could not attend and would resign. It would be difficult for members with clinical schedules to commit to attending on a regular basis if meetings were held during the day. It was confirmed that meetings are open to the public and must be held in Trenton.

### **IX. Report of Revenue and Expenditures**

Ms. Ray presented the Revenue and Expenditures Report (July 1, 2011 – June 30, 2012). There were no comments or questions.



## **X. Closing Comments**

Ms. Kirchner congratulated the Council on their work during a transformation process that started in December 2010 with the introduction of Ethics Training for State Officers. Approval of the Council's Code of Ethics resulted in transparency in discussions and actions and subsequently in redefining processes and procedures for awarding and monitoring funding for clinical research and treatment for autism. Members should be proud of their accomplishments and in knowing that the time and expertise they've devoted to their work has resulted in funding that supports and will continue to support the mission of the Council and the Statute that created the Council.

Ms. Kirchner recognized Dr. Daphne Robinson for her contributions in working with the Council and staff in defining and implementing an RFA process that supports the mission of the Council and is aligned with the national priorities for autism research.

Council staff was recognized by members for their timely response to requests and their work in supporting Council's initiatives.

## **XI. Adjournment**

Dr. Eggerding called for a motion to adjourn. MOTION by Ms. Goldfarb to adjourn was seconded by Dr. Evans.

MOTION passed with all in favor. The meeting was adjourned at 8:00 PM.